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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,099	08/23/2001	Rajiv Indravadan Modi	CAPH 8016US	2239

7590 02/10/2003

POLSTER, J. PHILIP
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EXAMINER

MELLER, MICHAEL V

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 02/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/935,099

Applicant(s)

MODI ET AL.

Examiner

Michael V. Meller

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 and 22-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-18 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear which active ingredient is "the active ingredient". There is no antecedent basis for "the active ingredient".

- new issue.
more
confused
now.

Applicant argues that the powder embodiment makes sense but if one of the "active ingredients" is coated, how can it then be a powder? When the active ingredient is in a coating suspension then it is not in a powder and when the active ingredient is granulated the coating is gone or at least damaged, thus the "protective barrier" is no more.

still
confusing.

Applicant argues that there is no protective barrier as there is a physical space. While this is interesting, something is still holding the "active ingredients" in place,

so if they are separated by a coating, how can they be only substantially together at the other end?

Also it is confusing which "active ingredient" is "the active ingredient", i.e. no antecedent basis for "the active ingredient". Further, there is no antecedent basis for

how does this amendment add anything to claim 15?

Art Unit: 1654

applicant's new amendment of "in said at least one layer". It is not clear which layer applicant is referring to.

Claim Rejections - 35 USC § 102

Claims 1, 3, 6-8, 15-18, and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by FR 6855.

Applicant argues that tetracycline is a bacteriostatic drug rather than a bacteriocidal drug but provides no evidence of this. Further, it is clear from FR 4430 (of record) that tetracycline maintains both bacteriostatic and bactericidal action against pathogenic germs such as *Lactobacillus acidophilus*. Also, as noted by Hawley's Condensed Chemical Dictionary, tetracycline is a known antibacterial/antibiotic, thus it meets the requirements of the claims.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by FR 5247.

Applicant's arguments are the same as above thus the rebuttal is the same as above.

Claim Rejections - 35 USC § 103

Claims 1-18 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR 5247 in view of FR 6855 and further in view of Black et al.

The same arguments and rebuttals to applicant's arguments are reiterated here. Applicant also argues that Black teaches administration of ampicillin and microorganisms in separate formulations, but they are administered at the same time, concurrently. Further, Black was relied upon to show that one would clearly have know that ampicillin and the like can be administered instead of tetracycline since ampicillin is routinely administered with *Lactobacillus acidophilus* as is evident from Black.

Claims 1-18 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR 6855 in view of Black et al.

The same arguments are applied here as above.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1654

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'M. Meller', with a long horizontal flourish extending to the right.

Michael V. Meller
Primary Examiner
Art Unit 1654

MVM
January 29, 2003